

10-29-09

DRAFT AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE 96th Meeting, November 16-17, 2009

Bethesda Marriott Hotel
5151 Pooks Hill Rd., Bethesda, MD 20814

Monday, November 16, 2009

8:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center,
Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflicts of Interest, Announcements

8:05 a.m. Committee Updates

- Update from the HHS Advisory Committee Blood Safety and Availability, Jerry Holmberg, Ph.D.,
Executive Secretary, Advisory Committee on Blood Safety and Availability (15')
- Dengue Virus Outbreak, Kay Tomashek, M.D., CDC (15')
- 2009 A/H1N1 Influenza Update and the Impact on Blood Safety and Availability, Alan Williams,
Ph.D., OBRR, FDA (15')

8:45 a.m. Topic I: Blood Donor Deferral for Malaria Risk Associated with Travel to Mexico

- A. Introduction, Sanjai Kumar, Ph.D., DETTD, FDA (25')
- B. Epidemiology of Malaria in Mexico, Paul Arguin, M.D., CDC (30')
- C. Risk of Malaria Infection Among US Travelers to Mexico, Bryan Spencer, MPH, American Red Cross
(25')
- D. Risk Analysis of Potential Exposure to Malaria in U.S. Travelers to Mexico, Mark Walderhaug, Ph.D.,
OBE, FDA (25')
- E. FDA Perspective, Sanjai Kumar, Ph.D., DETTD, FDA (15')

10:45 a.m. Break

11:00 a.m. Open Public Hearing

11:30a.m. Open Committee Discussion

F. Questions for the Committee

G. Committee Discussion

12:30 p.m. Lunch

10-29-09

1:30 p.m. Topic II: Study Designs (Phases 3 and 4) for Product Development of Human Platelets Using the Cerus INTERCEPT Blood System for Pathogen Inactivation

A. Introduction, Jaro Vostal, M.D., Ph.D., DH, OBRR, FDA (15')

B. The Role of Platelets in Acute Lung Injury, Klaus Ley, M.D., La Jolla Institute for Allergy and Immunology, University of California, San Diego (15')

C. Three-armed trial with Regular, Intersol and PRT-platelets, Jean-Louis. Kerkhoffs, M.D, Sanquin Blood Bank South West Region, Rotterdam, the Netherlands (15')

D. Cerus Presentations (60')

Carol Moore, VP Regulatory Affairs, Quality and Clinical

Laurence Corash, M.D., Senior VP, Clinical Research and Medical Affairs,
Chief Medical Officer

Claire Sherman, Ph.D. , Senior Biostatistician

Georges Andreu, M.D. Institut National de Transfusion Sanguine (National Institute of Transfusions Medicine), Executive Board for the Interdisciplinary European Society for Haemapheresis and Haemotherapy, France

Gordon Rubinfeld, M.D., M.Sc., Senior Scientist, Sunnybrook Health Sciences Centre,
Toronto, ON

E. FDA Review, Nisha Jain, M.D., DH, OBRR, FDA (15')

F. FDA Statistical Considerations, Jessica Kim, Ph.D., OBE, FDA (15')

3:45 p.m. Break

4:00 p.m. Open Public Hearing

4:30 p.m. Open Committee Discussion

E. Questions for the Committee

F. Committee Discussion

5:30 p.m. Adjournment

Tuesday, November 17, 2009

8:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflicts of Interest, Announcements

8:15 a.m. Topic III: Blood Pressure and Pulse as Blood Donor Eligibility Criteria

A. Introduction, Toby Silverman, M.D., OBRR, FDA (20')

10-29-09

- B. Pathophysiology of Syncope in the Context of Blood Donation, Wouter Wieling, M.D., Academic Medical Center, Amsterdam (35')
- C. The ARC Donor Hemovigilance Program: Evidence-based selection criteria to protect blood donors, Anne Eder, M.D., Ph.D., American Red Cross (20')
- D. The Role Of Pulse And Blood Pressure Among Other Predictors Of Donor Reactions, Peter Tomasulo, M.D., Blood Systems (25')
- E. Mitigating Adverse Reactions in Blood Donors, Christopher France, Ph.D., Ohio University (20')

10:15 a.m. Break

10:30 a.m. Open Public Hearing

11:00 a.m. Open Committee Discussion

F. Questions for the Committee

G. Committee Discussion

12:00 p.m. Lunch

1:00 p.m. Topic IV: Public Health Need and Performance Characteristics for Over-the-Counter Home-Use HIV Test Kits

A. Introduction, Elliot Cowan, Ph.D., DETTD, OBRR, FDA (20')

B. CDC Perspectives on the Role of Home-Use HIV Test Kits, Bernard Branson, MD, CDC/CCID (20')

C. Risk Analysis for Home-Use HIV Test Kits, Richard Forshee, Ph.D., CBER/OBE (30')

2:15 p.m. Open Public Hearing

3:00 p.m. Open Committee Discussion

D. Questions for the Committee

E. Committee Discussion

3:30 p.m. CLOSED SESSION

5:30 p.m. Adjournment